UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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VIVIAN RIVERA-ZAYAS, as the Proposed Administrator of the Estate of ANA MARTINEZ, Deceased,

Plaintiff,

-*against*-

OUR LADY OF CONSOLATION GERIATRIC CARE CENTER, OUR LADY OF CONSOLATION GERIATRIC CARE CENTER d/b/a OUR LADY OF CONSOLATION NURSING AND REHABILITATIVE CARE CENTER, and OUR LADY OF CONSOLATION NURSING AND REHABILITATIVE CARE CENTER,

Defendants.

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Docket No:
2:20-cv-05153-NGG-SIL

MEMORANDUM OF LAW SUBMITTED BY DEFENDANTS IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF'S COMPLAINT PURSUANT TO FED. R. CIV. P. 12(b)(1) and 12(b)(6)

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PRELIMINARY STATEMENT

Ana Martinez ("Mrs. Martinez/patient") was a resident of OLOC from January through March 2020, during the early days of the COVID-19 pandemic. OLOC had in place specific infection control protocols to help mitigate the spread of COVID-19 within its facility, based on medical and scientific guidelines at that time to combat this unprecedented public health emergency. Nonetheless, Mrs. Martinez began to show symptoms of COVID-19 at the end of March 2020, ultimately leading to her hospitalization and death on April 1, 2020. While at OLOC, the patient received multiple COVID-19 countermeasures to treat her suspected COVID-19 and its sequelae.

Plaintiff criticizes the steps that OLOC took to prevent the spread of COVID-19 in its facility. However, as will be explained below, the patient's injuries arose out of the administration and use of multiple "covered countermeasures" to combat COVID-19, which triggers the immunity and preemption provisions of the Public Readiness and Emergency Preparedness Act ("PREP Act"), thereby barring plaintiff's claims. This action is also clearly barred by New York's Emergency or Disaster Treatment Protection Act ("EDTPA"), which affords broad-based immunity to healthcare providers where a patient's care was impacted by decisions and activities

related to the prevention and treatment of COVID-19. Since plaintiff's allegations specifically invoke the sweeping immunity protections of the EDTPA, the complaint must be dismissed.

No matter how artfully pled or how hard plaintiff attempts to obscure the allegations in order to avoid the federal PREP Act claim and the New York state immunities, the complaint cannot be interpreted as anything other than a frontal attack on the diagnosis and care of COVID-19. These claims wholly trigger the applicable federal and state immunities, since the COVID-19 related care in question relates to the administration of covered countermeasure, as defined by the PREP Act, and invokes the liability protections of the EDTPA. Accordingly, OLOC respectfully asks this Court to dismiss this action with prejudice, pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

PROCEDURAL HISTORY AND PLAINTIFF'S CLAIMS

On September 30, 2020, plaintiff filed an Amended Verified Complaint in New York Supreme Court, Kings County, alleging state law claims for negligence, wrongful death, violations of New York's Public Health Law and gross negligence. More specifically, plaintiff is critical of the efforts made by OLOC to maintain a system for identifying, preventing and controlling infections in their facility, allegedly leading to the death of Mrs. Martinez on April 1, 2020 from COVID-19. Plaintiff is further critical of the infection control measures that were unquestionably in place, alleging that OLOC "failed to take proper precautions to help prevent the development of infections prior to and leading up to the COVID-19 pandemic." (*See* Amended Verified Complaint, at ¶¶ 1, 4, attached to Declaration as **Exhibit "A"**).

On October 26, 2020, OLOC timely removed this action to federal court, pursuant to 28 U.S.C. §§ 1331, 1367, 1441, 1442(a)(1) and 1446, and the PREP Act, 42 U.S.C. §§ 247d-6d, 247d-6e. (*See* Notice of Removal, **Exhibit "B"**). On January 26, 2021, this Court accepted the amended

briefing schedule, wherein OLOC's motion to dismiss shall be served by February 5, 2020; the Court also granted the parties' request for an expansion of the page limit for these moving papers to 35 pages.

STATEMENT OF FACTS

On January 8, 2020, the then 78-year-old patient presented to OLOC, a skilled senior nursing and rehabilitative care facility, upon transfer from Good Samaritan Hospital where she was treated for cutaneous abscess of buttocks and cellulitis. In the months that followed, the patient received nursing and rehabilitative care, without incident. (*See* Medical Records of Our Lady of Consolation Nursing and Rehabilitation, attached to Declaration, as **Exhibit "C").**

On March 12, 2020, in an effort to ensure the health and safety of its residents and in compliance with the guidelines, OLOC temporarily suspended all visitors from its facility to prevent the spread of COVID-19. Nurse Mary Ellen Haywood communicated this to plaintiff Vivian Rivera-Zayas, the patient's daughter. On March 21, 2020, the nursing staff noted that the patient had a dry cough; she denied shortness of breath and her temperature was 97.4 °F. On March 23, 2020, the patient's temperature was 99.6 °F and her oxygen levels were 95% on room air; no cough was noted. On that day, Social Worker Danielle Rank spoke with plaintiff to notify her that since some patients were experiencing respiratory symptoms, the decision was made to close the unit as per DOH guidelines. (*Id.,* Resident Progress Notes at pp. 6-9).

On March 24, 2020, Mrs. Martinez had an episode of watery diarrhea; no shortness of breath was noted. On March 25, 2020, the patient had a temperature of 96.6 °F and an occasional cough; no shortness of breath or respiratory distress was noted. (*Id.* at pp. 4-5). Due to suspicions for COVID-19 and the infection prevention and control protocols in place at OLOC, Droplet Precautions were put in place for the patient, which involved: 1.) confining residents to their room

or affected community for at least 7 days or until 24 hours after resolution of fever without medication; 2.) if resident has a roommate, draw curtains if resident is 3 feet or less from roommate; and 3.) proper PPE must be worn and hand hygiene, as per policy. (*Id.* at. PDF p. 435). Judy Raziano, RN, CRRN (Infection Preventionist) issued a "Precaution Notification" on this day that droplet precautions were in place for this patient. (*Id.;* Resident Progress Notes, at p. 6.).

On March 26, 2020, the patient complained of shortness of breath while in bed, which was relieved when the head of her bed was elevated. The following day, March 27, 2020, the patient complained of aches and pains, which were relieved with Tylenol. Tylenol was administered the following day as well. In the days that followed, the patient was generally comfortable, with no acute distress noted; episodes of discomfort were relieved with Tylenol. On the morning of March 30, 2020, the patient complained of malaise and feeling tired. As the day continued, the patient's oxygen levels decreased and wheezing was noted, as were changes in the patient's level of consciousness. Supplemental oxygen was provided via nasal cannula. The decision was made to transfer the patient to Good Samaritan Hospital for further evaluation of hypoxia (oxygen deficiency). (*Id.,* Resident Progress Notes at pp. 1-4). According to the Amended Complaint, the patient sadly passed away on April 1, 2020 from complications due to COVID-19.

LEGAL STANDARDS

A. 12(b)(1) – Lack of Subject Matter Jurisdiction

"A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). Although when considering a motion to dismiss pursuant to Rule 12(b)(1), a court must accept as true all material factual allegations in the

complaint, "[i]n resolving a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), a district court … may refer to evidence outside the pleadings." *Makarova*, 201 F.3d at 113. Evidentiary matters may be presented by affidavit or otherwise. *Broidy Capital Mgmt. LLC v. Benomar,* 944 F.3d 436, 441 (2nd Cir. 2019). The burden of proving jurisdiction is on the party asserting it, but the court does not draw "argumentative inferences" and "will take as true uncontroverted factual allegations." *Robinson v. Overseas Military Sales Corp.*, 21 F.3d 502, 507 (2d Cir. 1994).

B. 12(b)(6) – Failure to State a Claim

In considering a motion to dismiss pursuant to Rule 12(b)(6), the Court construes the claims liberally, "accepting all factual allegations in the complaint as true and drawing all reasonable inferences in the plaintiff's favor." *Chambers v. Time Warner, Inc.,* 282 F.3d 147, 152 (2nd Cir. 2002). However, the Court need credit as true factual allegations only, not "'legal conclusions'" in a claim or "'threadbare recitals of the elements of a cause of action, supported by mere conclusory statements.'" *Harris v. Mills,* 572 F.3d 66, 72 (2nd Cir. 2009), *quoting Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) [internal quotations omitted]. "To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.'" *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2nd Cir. 2007) [quotation omitted].

Indeed, to survive a motion to dismiss, each claim must set forth sufficient factual allegations "to state a claim to relief that is plausible on its face." *Ashcroft,* 556 U.S. at 678. In determining the sufficiency of a claim under Rule 12(b)(6), the Court may consider not only the allegations on the face of a pleading, but also "[d]ocuments that are attached to the complaint or incorporated in it by reference" which are deemed part of the pleading." *Roth v. Jennings,* 489

F.3d 499, 509 (2d Cir. 2007). In addition to documents referenced in the complaint, courts may also consider documents that plaintiff relied on in bringing suit, which are either in plaintiff's possession or that plaintiff knew of and relied on when bringing suit or matters of which judicial notice may be taken. *See Chambers v. Time Warner, Inc.,* 282 F.3d 147, 152–53 (2nd Cir. 2002). Although the court has the option to convert a Rule 12(b)(6) motion to a Rule 56 motion and permit additional discovery as it deems appropriate, such conversion is not required if the plaintiff had actual notice of the information and documents relied upon in the movant's papers. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152–53 (2d Cir. 2002), *quoting Cortec Indus., Inc. v. Sum Holding L.P.,* 949 F.2d 42, 48 (2d Cir.1991).

Courts have held that a plaintiff's medical records are properly considered by a court in determining a Rule 12(b)(1) or 12(b)(6) motion where they are integral to the complaint and there is no dispute regarding the records' authenticity. *See, e.g., Brown v. Defrank,* 06 Civ. 2235(AJP), 22006 WL 3313821, *16 (S.D.N.Y. Nov. 15, 2006); *Brown v. Pangia*, No. 11 CIV. 6048 AT, 2014 WL 2211849, at *1 (S.D.N.Y. May 27, 2014) [considering plaintiff's medical records in addition to complaint because of plaintiff's explicit reliance on records in drafting complaint]. District courts may take also judicial notice of public documents or matters of public record, including the records of administrative bodies, such as the FDA, on a motion to dismiss. *See Casey v. Odwalla, Inc.* 338 F.Supp.3d 284 (S.D.N.Y. 2018); *citing Porrazzo v. Bumble Bee Foods, LLC.*, 822 F.Supp.2d 406, 411 (S.D.N.Y. 2011) and *Christman v. Skinner*, 468 F.2d 723 (2d Cir. 1972); *e.g., Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2nd Cir. 2016) [taking judicial notice of FDA guidance document in considering motion to dismiss]; *Simon v. Smith & Nephew, Inc.*, 990 F.Supp.2d 395, 401 n.2 (S.D.N.Y. 2013) [taking judicial notice of public records on FDA website].

C. Chevron Deference

The section that follows discusses the PREP Act, including the plain language of the statute and the Declaration and Advisory Opinions that govern its application to the COVID-19 emergency. Through the PREP Act, Congress vested the Secretary of HHS with the authority to determine whether a public health emergency exists and to issue a Declaration recommending the administration of specified countermeasures to combat that emergency. 42 U.S.C.A. § 247d-6d(b). Judicial review of the Secretary's actions are limited. Indeed, the plain language of the PREP Act states: "[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection. *Id.*, § 247d-6d(b)(7).

The COVID-19 Declaration, and the Advisory Opinions fully incorporated therein, are entitled to *Chevron* deference by this Court. *See Chevron U. S. A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *Chevron* instructs that a court facing statutory ambiguity should endorse the reasonable interpretation by the implementing agency, in this case HHS, since the agency's expertise enables a well-founded assessment of which reading best fits the statutory scheme. In *Chevron*, the Court held: "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency. We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations." *Id*. at 843-44.

Thus, since Congress has expressly delegated the application of the PREP Act to a given public health emergency to HHS, the interpretative proclamations of HHS are controlling on federal courts. *See, e.g., Kruse v. Wells Fargo Home Mortg., Inc.,* 383 F.3d 49 (2d Cir. 2004)

[*Chevron* deference was due to Department of Housing and Urban Development's ("HUD") policy statement where Congress delegated authority to HUD to make rules carrying force of law and agency interpretation was promulgated in exercise of that authority].

APPLICABLE LAW

The PREP Act and the EDTPA provide clear bases for dismissal of plaintiff's claims. The PREP Act provides sweeping immunity to covered persons such as OLOC for injuries arising out of or related to the administration or use of "covered countermeasures" during a public health emergency declared under the PREP Act, which is this case were administered to prevent and mitigate the spread of COVID-19. Similarly, the EDTPA was enacted to promote public health, safety, and welfare by broadly protecting health care facilities and providers from liability that may result from the treatment of individuals with COVID-19 or from treatment that is impacted by decisions or activities in response to or resulting from the COVID-19 outbreak. OLOC is, therefore, immune from suit under both the PREP Act and the EDTPA, and the Amended Complaint, therefore, must be dismissed under both federal and state law.

I. THE PREP ACT

A. Plain Language of the PREP Act

The PREP Act, enacted on December 30, 2005, is a unique statutory scheme that lies dormant until it is invoked by the Secretary of Health and Human Services (the "Secretary") at the time of a public health emergency. Congress enacted the PREP Act to encourage and coordinate a thorough, rapid, and comprehensive response to declared public health emergencies. 42 U.S.C.A. § 247d-6d(b). It grants broad immunity to covered persons, such as front-line healthcare workers and other entities who deploy approved countermeasures, for liability for claims of loss

related to the administration or use of covered countermeasures so that they may combat the emergency without fear of later litigation.

The PREP Act authorizes the Secretary to issue a Declaration, subject to amendment, that a specified disease or condition is a public health emergency for a certain time period.[1] Once made, the Declaration grants liability immunity to "covered persons" against any claim of loss caused by or relating to the use of identified countermeasures. It also creates a compensation fund as the exclusive remedy for parties who suffer serious physical injuries or death from the use of the countermeasures. Specifically,

> if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

42 U.S.C.A. § 247d-6d(b)(1). The Declaration under the PREP Act must specify the covered countermeasures identified to respond to the declared public health emergency for which immunity is granted. Once the Declaration is made,

> a covered person ***shall*** be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure. [emphasis added]

42 U.S.C.A. § 247d-6d(a)(1).

[1] For example, the Secretary previously issued Declarations pertaining to the H1N1 pandemic of 2009-10 and the Zika outbreak of 2016-17.

Under the Act, immunity applies "to any claim of loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C.A. § 247d-6d(a)(2)(B). "Claims of loss" under the Act are broad and include any type of loss including death; physical mental, or emotional injury, illness, and disability; fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property. 42 U.S.C.A. § 247d-6d(a)(2)(A).

The PREP Act expressly preempts any claim filed in state court for negligence or violation of state law that arises out of the administration or use of covered countermeasures through the creation of an exclusive federal cause of action. The preemption language is unequivocal, *to wit*: "no State or political subdivision of the State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirements that – (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the … use …or administration by qualified persons of the covered countermeasure…." 42 U.S.C.A. § 247d-6d(b)(8).

The exclusive remedy for death or serious injury resulting from the administration or use of a covered countermeasure is a fully-funded, no-fault-type compensation program designated by Congress as the "Covered Countermeasure Process Fund" (the "Fund"). 42 U.S.C.A. § 247d-6e. The Fund, similar to Workers' Compensation or the National Vaccine Injury Compensation Program, was established to provide timely, uniform, and adequate compensation to eligible individuals for covered injuries in place of expensive and uncertain litigation. The "sole exception to the immunity from suit and liability of covered persons" provided in the PREP Act is a federal cause of action brought for death or serious physical injury resulting from willful misconduct, as

statutorily defined, which suit must be brought in the United States District Court for the District of Columbia after exhaustion of remedies under the Fund. 42 U.S.C.A. § 247d-6d(d)(e).

Among the covered countermeasures included in the PREP Act are: "a qualified pandemic or epidemic product"; "a security countermeasure"; a drug; and a biologic product, all as defined by federal law, and therapeutics and devices that have been authorized for emergency use in accordance with the Federal Food, Drug, and Cosmetic Act. Unique to the response to COVID-19, respiratory protective devices were added to the list of covered countermeasures by The Coronavirus Aid, Relief, and Economic Security ("CARES") Act § 3103, Pub. L. No. 116-136 (March 27, 2020). *See* 42 U.S.C.A. § 247d-6d.

The PREP Act defines a "covered person" entitled to immunity to include a "program planner" and a "qualified person" who administers or dispenses covered countermeasures. 42 U.S.C.A. § 247d-6d(i). A "qualified person" broadly includes any "licensed health professional or other individual who is authorized to prescribe, administer, or dispense [covered] countermeasures under [applicable state law]." 42 U.S.C.A. § 247d-6d(i)(8). A "program planner" includes a person who supervises or administers a program with respect to the administration or use of a covered countermeasure. 42 U.S.C.A. § 247d-6d(i)(6). Through the Declaration and Advisory Opinions issued by HHS, as outlined below, the definition of a "covered person" has been expanded to respond to the unprecedented emergency presented by the COVID-19 pandemic.

B. COVID-19 Declaration

On March 10, 2020, HHS Secretary Alex M. Azar issued the required Declaration invoking the PREP Act for the COVID-19 pandemic, effective February 4, 2020, determining that "the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease COVID-19

constitutes a public health emergency."[2] The Declaration delineated that the PREP Act's liability immunity was in effect for the distribution, administration, or use of one or more covered countermeasures and recommended the administration and use of "Covered Countermeasures" to combat COVID-19. "Covered Countermeasures" were defined as "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product." *Id.,* sec. VI.

The Declaration confirmed that the PREP Act's liability immunity applies to "Covered Persons", including a "program planner" and "qualified person", defined as a person who "supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure" and "a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the Covered Countermeasure was prescribed, administered, or dispensed" respectively. *Id.*, sec. V.

The Declaration defines the "administration" of covered countermeasures to include the: "physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients…." *Id.*, sec. IX. Administration also includes activities related to "management and operation of countermeasure programs ….." *Id.*

The Declaration states:

[2] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 15198-01 (March 10, 2020) ("Declaration" or "COVID-19 Declaration").

> [c]laims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under the Act. Under the definition, these liability claims are precluded if they allege an injury caused by a countermeasure, or if the claims are due to manufacture, delivery, distribution, dispensing, or ***management and operation of countermeasure programs*** at distribution and dispensing sites.

Id. (Emphasis added). The COVID-19 Declaration has been amended five times, on April 15, 2020, June 8, 2020, August 19, 2020, December 2, 2020, and January 28, 2021, each time broadening the scope of the PREP Act as applied to the emergency response to this unique global pandemic.[3]

Significantly, the Fourth Amendment to the Declaration, issued on December 3, 2020, ***directs that the Declaration be construed in accordance with the five Advisory Opinions on the PREP Act issued by HHS*** and fully incorporates these Opinions into the Declaration.[4]

This Amendment also makes explicit that "administration" of covered countermeasures means not only the physical provision of countermeasures to recipients, but also "activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, ***management and operation of countermeasure programs***, or

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[3] Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 21012-02, at 21013-14 (April 15, 2020) [adding approved respiratory devices to list of covered countermeasures, pursuant to CARES Act]; Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 35100-01, at 35101-02 (June 8, 2020) [clarifying that covered countermeasures include countermeasures that "limit the harm COVID-19 … might otherwise cause."]; Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 52136-01 (Aug. 19, 2020) [declaring that categories of disease representing a public health emergency include not only to COVID-19, but also "other diseases, health conditions, or threats that may have been caused by COVID-19 …."]; Fifth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID-Amendment5.aspx (January 28, 2021) [adding additional categories to the definition of "qualified persons," including professionals qualified to administer the COVID-19 vaccine under the laws of any state].

[4] Fourth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 79190 (Dec. 3, 2020) ("Fourth Amendment").

management and operation of locations for the purpose of distributing and dispensing countermeasures." *Id.*, sec. IX. (Emphasis added). The Amendment further explicitly provides that claims regarding the failure to administer a covered countermeasure may also implicate the preemption and immunity provisions under the PREP Act.

The Fourth Amendment further recognizes the "substantial federal legal and policy issues" and "substantial federal legal and policy interests", within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g.*, 545 U.S. 308 (2005), in having a unified, national response to COVID-19 through a uniform interpretation of the PREP Act.[5] *Id.* In *Grable*, the Supreme Court held that federal question jurisdiction is warranted if the national interest in providing a federal forum is sufficiently "substantial". The *Grable* Court discussed the longstanding variety of federal "arising under" jurisdiction where, in certain cases, federal-question jurisdiction will lie over pleaded state-law claims that implicate significant federal issues. HHS recognizes that only a uniform federal approach in analyzing and applying the PREP Act will meet the "whole-of-nation response" that is necessary to address the COVID-19 pandemic.

C. HHS Advisory Opinions

The five Advisory Opinions issued by the HHS Office of General Counsel ("OGC"), which have been incorporated into the Secretary's Fourth Amendment to the Declaration for the purpose of its construction, illustrate the expansive scope of the PREP Act and its immunities for individuals and organizations that administer or use covered countermeasures to combat COVID-19.

The most recent and Fifth Advisory Opinion, issued on January 8, 2021, is significant because it addresses exclusive federal jurisdiction in cases invoking the PREP Act and also

[5] Fourth Amendment to the Declaration, sec. X1.

confirms that the PREP Act applies to suits concerning the non-use of covered countermeasures against COVID-19.

In this Opinion, HHS significantly declared that the "PREP Act is a 'Complete Preemption' Statute", stating:

> [t]he *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both.
>
> Once complete preemption attaches, the district court is usually obligated to dismiss the case as pleaded, either because no federal cause of action is alleged or the exclusive initial venue is a federal administrative agency.[6]

(Emphasis in original).

This Opinion also highlights the "relating to" language of the Act and explains that any "black-and-white" view that the PREP Act only applies to use versus non-use is in direct contravention of the plain language of the PREP Act, which extends immunity to anything "relating to" the administration of a covered countermeasure. *Id.* at p. 3. The Opinion asserts that ***the Secretary's COVID-19 Declaration includes both action and inaction*** with respect to covered countermeasures against COVID-19, and is critical of lower court decisions that limit application of the PREP Act to allegations of "use". Indeed, HHS explained:

> [d]istrict courts appear to have labored hard attempting to ordain whether the non-use of a covered countermeasure triggers the PREP Act and its complete preemption regime.
>
> ***
>
> Some district courts have interpreted the scope of the immunity in subparagraph (B) as requiring "use." Under this view, if a covered countermeasure were not used, then there is no PREP Act immunity.

[6] *See* Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision, p. 2, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf (January 8, 2021) ("Advisory Opinion 21-01").

> According to one court, "[t]here is simply no room to read [the PREP Act] as equally applicable to the non-administration or non-use of a covered countermeasure." Lutz v. Big Blue Healthcare, Inc., ___F. Supp. 3d ___, 2020 WL 4815100, at *8 (D. Kan. 2020) (emphasis in original) (granted remand motion).
>
> However, this "black and white" view clashes with the plain language of the PREP Act, which extends immunity to anything "relating to" the administration of a covered countermeasure.

Id. at pp. 2-3. Notably, this Opinion highlights the importance of "program planners" in the emergency response to COVID-19, confirming that ***"decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by PREP Act."*** *Id. a*t p. 4. (Emphasis added).[7]

Significantly, HHS' interpretation of the PREP Act, as set forth in the Fifth Advisory Opinion, was recently adopted by the District Court for the Central District of California in *Gilbert Garcia, et al. v. Welltower OpCo Group LLC, et al.*, 8:20-cv-02250-JVS-KESx (C.D.Cal. Jan. 29, 2021), attached hereto as **Exhibit "D"**.[8] Like in this case, the allegations in *Garcia* involved the defendant senior living facility's alleged failure to implement appropriate infection control measures in preparing for and preventing COVID-19. Plaintiffs contended that the PREP Act was limited to the physical provision of a countermeasure to a recipient and did not extend to the administration of infection control programs. The court rejected this argument, ruling that

[7] OLOC urges this Court to not follow the recent decision in *Dupervil v. Alliance Health Operations, LCC,* No. 20CV4042PKCPK, 2021 WL 355137, at *9 (E.D.N.Y. Feb. 2, 2021), wherein the court refused to give *Chevron* deference to HHS' interpretations of the PREP Act. Although recognizing: 1.) Congress assigned the Secretary of HHS with the responsibility of providing relevant conditions in the Declaration with regard to the PREP Act; and 2.) the Secretary's Fourth Amendment to the Declaration states that the Declaration "must be construed in accordance with the Advisory Opinions" which are expressly incorporated into the Declaration, the court impermissibly rejected HHS' interpretation of the PREP Act, as set forth in Advisory Opinion 21-01. Since Congress expressly delegated the application of the PREP Act to HHS, the Declaration and Advisory Opinions are controlling on this Court, pursuant to *Chevron U. S. A. Inc.*, 467 U.S. at 843-44.

[8] As stated on page 17 of this Tentative Order, it was decided on the papers and becomes the Order of the Court if no request for oral argument is made.

decision-making leading to the nonuse of covered countermeasures is expressly covered by the PREP Act. The court, therefore, denied plaintiffs' motion to remand and dismissed the complaint for failure to state a cause of action.

In sum, the Fifth Advisory Opinion highlights the broad scope of immunity and preemption under the PREP Act and notably underscores the importance of federal jurisdiction for all claims "relating to" the administration of a covered countermeasure. This is consistent with the Advisory Opinions that precede it, as outlined below.

The first Advisory Opinion, published on April 17, 2020, as modified on May 19, 2020, is an "omnibus advisory opinion" that addresses questions regarding the scope of PREP Act immunity during the COVID-19 pandemic, and emphasizes: "[u]nder the PREP Act, immunity is broad. As a general matter, a covered person is immune from liability for all claims for loss except for willful misconduct that proximately caused death or serious injury …." It also confirms that "PREP Act immunity applies to any 'covered person' with respect to all 'claims for loss' caused by, arising out of, relating to, or resulting from the 'administration' or the 'use' of a 'covered countermeasure ….'"[9]

Thus, PREP Act immunity is far-reaching and includes "any activity that is part of an authorized emergency response at the federal region, regional, state, or local level." Moreover, this Opinion emphasizes that: "PREP Act immunity must be read in light of the PREP Act's broad, expression-preemption provision." *Id.* at p. 2. With respect to "covered countermeasures", the Advisory Opinion noted that the number of products used for COVID-19 as qualified pandemic or epidemic products were too numerous to list and, therefore, the Opinion includes a link to a list

[9] *See* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, pp. 1, 7 https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf (May 19, 2020) ("Advisory Opinion").

of those products not yet approved by the FDA but covered by FDA Emergency Use Authorizations. This Opinion re-asserts that "[a]ny drug, device, or biological product that is approved, cleared, or licensed by the FDA and is used to diagnose, mitigate, prevent, treat, cure, or limit the harm of COVID-19 is a covered countermeasure." *Id.* at p. 4.

The second Advisory Opinion, also issued on May 19, 2020, discusses the breadth of the "different from, or is in conflict with" preemption language of the PREP Act, noting that courts have broadly interpreted similar preemption clauses and that such preemption language "sweeps widely" and preempts any language that "deviates from [requirements] imposed by federal law." *Id., citing Wolicki-Gables v. Arrow Int'l., Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (*quoting Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008*)); Nat'l Meat Ass'n. v. Harris*, 565 U.S. 452, 459, 461 (2012).[10] This Opinion further states that, under the PREP Act, "Congress gave the secretary virtually unreviewable authority to immunize and designate a 'qualified person' to use a 'covered countered measure.'" *Id.* at p.5, fn 9.[11]

The fourth Advisory Opinion, issued on October 23, 2020, acknowledged the changing medical and scientific knowledge surrounding COVID-19 and the uncertainty this has caused to those combatting this "unprecedented global challenge." HHS recognized that these uncertainties have presented potential legal risk, which may "hinder essential efforts" to "combat the pandemic,"

[10] *See* Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf (May 19, 2020).

[11] The third Advisory Opinion addressed three vaccination issues under the PREP Act and re-asserted the complete preemptive effect of the PREP Act with respect to states laws in conflict with activities authorized by the PREP Act Declaration. *See* Advisory Opinion 20-03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf (October 23, 2020).

and reiterates that "the PREP Act exists, in part, to remove legal uncertainty and risk."[12] This Opinion also clarifies that "administration" of covered countermeasures, as defined under the Act, extends beyond the mere physical provision of covered countermeasures and encompasses "activities related to management and operation of programs and locations for providing counter-measures to recipients." *Id.* at p. 7. Thus, the Advisory Opinion plainly establishes that the Secretary's COVID-19 Declaration "broadly extends PREP Act immunity" to ***include both action and inaction*** with respect to efforts to prevent community-based transmission of COVID-19. *Id.* at p. 2.

II. THE EDTPA

In enacting the EDTPA, the New York State Legislature recognized the public health emergency created by COVID-19 and that medical treatment to patients during this time "is a matter of vital state concern affecting the public health, safety and welfare of all citizens." With this purpose, the EDTPA promotes "the public health, safety and welfare of all citizens" by protecting health care providers and facilities from liability that may result from acts or omissions relating to the diagnosis, prevention or treatment of COVID-19. N.Y. Pub. Health Law § 3080 (McKinney).

The Act applies broadly and states:

> any health care facility or health care professional shall have immunity from any liability, civil or criminal, for any harm or damages alleged to have been sustained as a result of an act or omission in the course of arranging for or providing health care services, if:

[12] *See* Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act (October 23, 2020) ("Advisory Opinion 20-04"), p.1, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf

> (a) the health care facility or health care professional is arranging for or providing health care services pursuant to a COVID–19 emergency rule or otherwise in accordance with applicable law;
>
> (b) the act or omission occurs in the course of arranging for or providing health care services and the treatment of the individual is impacted by the health care facility's or health care professional's decisions or activities in response to or as a result of the COVID–19 outbreak and in support of the state's directives; and
>
> (c) the health care facility or health care professional is arranging for or providing health care services in good faith.

N.Y. Pub. Health Law § 3082(1) (McKinney). For purposes of this section, "health care services" are defined as:

> services provided by a health care facility or a health care professional, regardless of the location where those services are provided, that relate to:
>
> (a) the diagnosis, prevention, or treatment of COVID-19;
>
> (b) the assessment or care of an individual with a confirmed or suspected case of COVID-19; or
>
> (c) the care of any other individual who presents at a health care facility or to a health care professional during the period of the COVID-19 emergency declaration.

Id. The only exception to immunity is if:

> the harm or damages were caused by an act or omission constituting willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm by the health care facility or health care professional providing health care services, provided, however, that acts, omissions or decisions resulting from a resource or staffing shortage shall not be considered to be willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm.

N.Y. Pub. Health Law § 3082(2) (McKinney) (emphasis added).

Through the enactment of the EDTPA, New York created sweeping immunity to shield health care providers from liability for any injuries allegedly resulting from acts or omissions that relate to the prevention or treatment of COVID-19, or to the care of a patient with a confirmed case of COVID-19. The only exception to immunity is where an individual's alleged injuries were caused by gross negligence or willful or intentional criminal misconduct.

ARGUMENT

I. OLOC IS A COVERED PERSON UNDER THE PREP ACT.

OLOC is both a "program planner" and "qualified person" under the PREP Act. "Program planners" are defined by the PREP Act as those who: "***supervised or administered a program*** with respect to the administration, dispensing … or use of a [covered countermeasure], ***including a person who has established requirements*** ... in accordance with a declaration under subsection (b)." 42 U.S.C.A. § 247d-6d (West) (emphasis added). Notably, a private sector employer or community group can be a program planner when it carries out the described activities.[13] Indeed, HHS has confirmed that a senior living community such as OLOC meets the definition of a "program planner" to the extent that it supervises or administers a program with respect to the administration or provision of covered countermeasures.[14]

In the context of a facility like OLOC, the administration and distribution of covered countermeasures are part of and relate to its infection control program against COVID-19. Indeed, plaintiff alleges that New York State law requires that OLOC "maintain an infection control program … to help prevent the development and transmission of disease and infection…." (*See* Complaint, at ¶ 51). Plaintiff further alleges that federal law requires that OLOC "maintain a sufficient Infection Prevention and Control Program, and that the facility maintains and utilizes

[13] Advisory Opinion, p. 6.
[14] *See* August 14, 2020 Letter from HHS, attached to Declaration as **Exhibit "E".**

sufficient Personal Protective Equipment ("PPE"), including gloves, gowns and masks." (*See* Complaint, at ¶ 52). As evident by the infection control protocols in place at OLOC, as documented in the patient's medical records and as tacitly conceded in the Complaint (¶ 58), OLOC engaged in affirmative acts as part of its infection control program relating to multiple covered countermeasures to prevent the spread of COVID-19 throughout the facility.

For example, on March 12, 2020, OLOC temporarily suspended all visitors from the facility to prevent the spread of COVID-19. On March 21, 2020, when patients were experiencing respiratory symptoms, the decision was made to close the affected unit as per DOH guidelines. (Exhibit "C", Resident Progress Notes at pp. 6-9). Further protocols were put in place for patients with cases of suspected COVID-19, which included: 1) confining residents to their room or affected community for at least 7 days or until 24 hours after resolution of fever without medication; 2) if the resident had a roommate, drawing curtains if the residents were within 3 feet of one another; and 3) mandating that proper PPE be worn and hand hygiene maintained, as per policy. (*Id.* at. PDF p. 435). These activities and decision-making related to the use and management of these covered countermeasures to prevent community-based transmission of COVID-19 trigger the PREP Act.[15]

II. PLAINTIFF'S CLAIMS ARISE OUT OF COVERED COUNTERMEASURES

Plaintiff's allegations also establish that OLOC was engaged in the administration and use of covered countermeasures pursuant to the PREP Act. The PREP Act covers not only the active administration and use of covered countermeasures to combat COVID-19, but also extends to "any

[15] Defendants are also "qualified persons" under the PREP Act, which include any "licensed health professional or other individual who is authorized to prescribe, administer, or dispense [covered] countermeasures under [applicable state law]." 42 U.S.C.A. § 247d-6d(i)(8). HHS has also confirmed that a senior living community may be a "qualified person" when authorized to distribute or dispense covered countermeasures. (*See* Exhibit "E").

activity that is part of an authorized emergency response [to COVID-19] at the federal region, regional, state, or local level."[16] This includes ***decisions*** related to the use and management of covered countermeasures, including PPE, to prevent community-based transmission of COVID-19 to others.[17] Indeed, the COVID-19 Declaration "broadly extends PREP Act immunity" to include both action and inaction with respect to efforts to prevent community-based transmission of COVID-19, and the most recent Advisory Opinion confirms that the plain language of the PREP Act extends immunity "to anything ***'relating to'*** the administration of a covered countermeasure."[18]

The Fourth Amendment to the Declaration affirms that the "administration" of covered countermeasures includes "activities and decisions directly relating to … ***management and operation of countermeasure programs***",[19] and the most recent Advisory Opinion clarifies: "***decision-making*** that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by PREP Act."[20] (Emphasis added). Here, plaintiff indicates that covered countermeasures to prevent the spread of COVID-19 were not sufficiently used, thereby leading to the death of Mrs. Martinez from COVID-19. HHS had repeatedly declared that such claims invoke the PREP Act.

Though artfully pleaded, plaintiff's Amended Complaint in fact satisfies the PREP Act because it necessarily implicates the affirmative decisions made by OLOC to combat COVID-19 and for the specific care of the patient. As set forth above, there was a suspicion that the patient

[16] 42 U.S.C.A. § 247d-6d(a)(2)(B); Advisory Opinion, p. 2.

[17] Advisory Opinion 20-04.

[18] *See* Advisory Opinion 20-03, p. 2; Advisory Opinion 21-01, p. 3.

[19] Fourth Declaration, sec. IX. (Emphasis added).

[20] Advisory Opinion 21-01, p. 4. (Emphasis added.)

had COVID-19 on March 25, 2020, triggering the use of covered countermeasures such as Tylenol to treat the patient's fever and body aches, thermometers to track the patient's temperature, and supplemental oxygen via nasal cannula to treat the patient's respiratory distress. All of these are covered countermeasures under the PREP Act, which include any "any drug … any diagnostic, any other device … used to treat, diagnose, cure, prevent, or mitigate COVID-19…." including drugs or devices authorized by the FDA or via emergency use under the Federal Food, Drug & Cosmetic Act. [21]

However, even before that, OLOC was deeply engaged in infection control measures, which are specifically cited in the patient's chart. The Amended Complaint alleges that OLOC's negligence in maintaining a system for preventing and controlling infections led to the death of the patient from COVID-19, and references past failures to allegedly implement contact isolation protocols and ensure sufficient use of PPE, including gloves, masks, gowns, respirators and eye protection -- all covered countermeasures. (Complaint, at ¶¶ 1-3, 52, 57). The number of COVID-19 countermeasures are too numerous to list and, therefore, the initial Advisory Opinion includes a link to those countermeasures covered by FDA Emergency Use Authorizations.[22] The FDA provides information regarding these countermeasures at "FDA Combating COVID-19 with Medical Devices", which includes links to COVID-19 testing, PPE and other medical devices to combat COVID-19.[23] Notably, HHS has declared that an entity that complies with the requirements of the PREP Act and Declaration will not lose PREP Act immunity even if the measure at issue is not a "covered countermeasure".[24]

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[21] *See* 42 U.S.C.A. § 247d-6d(i)(1); Declaration, sec. VI; 21 C.F.R. § 868.5340 (nasal oxygen cannula); 21 CFR §§ 880.2200, 880.2900, 880.2910, 880.2920 (thermometers); https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=018337 (Tylenol)
[22] Advisory Opinion, p. 4.
[23] https://www.fda.gov/media/136702/download.
[24] Advisory Opinion, p. 4.

In sum, OLOC's infection control program and protocols as discussed above are indicative of, and relate to, the covered countermeasures employed by OLOC to combat COVID-19. In its role as a program planner, OLOC managed and operated a countermeasure program to prevent and mitigate COVID-19 as part of this comprehensive infection control program. As the Central District of California found in *Garcia*, allegations regarding these types of infection control measures "directly relate to covered countermeasures within the meaning of the PREP Act." (*See* Exhibit "D", p. 13). As such, since these protocols are the ways in which OLOC acted to "limit the harm such a pandemic or epidemic might otherwise cause",[25] as in *Garcia*, OLOC's activities and decisions invoke and are protected by the PREP Act.

III. PLAINTIFF'S CLAIMS ARE PREEMPTED BY THE PREP ACT'S ALTERNATIVE FEDERAL REMEDY, THEREBY WARRANTING DISMISSAL

Since plaintiff is alleging a claim of loss relating to the administration or use of a covered countermeasure in response to the COVID-19 emergency, her state law claims are completely preempted by the PREP Act's federal remedy, thereby warranting dismissal.

The preemption language of the PREP Act is unequivocal, providing: "no state or political subdivision of the state may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirements that – (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the … use …or administration by qualified persons of the covered countermeasures…." 42 U.S.C.A. § 247d-6d(b)(8). In the First and Second Advisory Opinions concerning the PREP Act Declaration with respect to COVID-19, the HHS Office of General Counsel confirms that the express preemption

[25] Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 35100-01, at 35101-02 (June 8, 2020) [covered countermeasures include countermeasures that "limit the harm COVID-19 … might otherwise cause."];

language in the PREP Act "sweeps widely" and should be broadly interpreted.[26] The Advisory Opinions establish that the PREP Act should be construed as a complete preemption statute based on a federal question, because the only viable claim under the Act lies under the Fund or in the District Court.[27]

The Declaration further reinforces that plaintiff's exclusive remedy under the PREP Act is the filing of a claim for benefits or compensation under the Fund. *See* 42 U.S.C.A. § 247d-6e. In the event plaintiff exhausts her remedies available under the Fund, plaintiff's sole remedy is a federal cause of action for death or serious physical injury proximately caused by willful misconduct, which action may only be filed in the United States District Court for the District of Columbia. 42 U.S.C.A. § 247d-6d(d)(e). Thus, this Court does not have jurisdiction to adjudicate plaintiff's claims.

The New York Appellate Division, Third Department ruled that the PREP Act's express preemption clause mandated the preemption of plaintiff's state common law claims in *Parker v. St. Lawrence Cty. Pub. Health Dep't*, 102 A.D.3d 140, 143 (3rd Dept. 2012). One of the few cases discussing the preemptive effect of the PREP Act in the context of a dismissal motion, the plaintiff in *Parker* brought a negligence and battery claim under state law against the defendants for their unauthorized vaccination of plaintiff's daughter in connection with the 2009 H1N1 influenza pandemic, and Defendants moved to dismiss for lack of subject matter jurisdiction on the ground of federal preemption under the PREP Act. *Id.* at 143. The court held:

> [c]onsidering the breadth of the preemption clause together with the sweeping language of the statute's immunity provision, we conclude that ***Congress intended to preempt all state law tort claims arising from the***

[26] *See* Advisory Opinion, p. 2; Advisory Opinion 20-02, p. 4.

[27] See Advisory Opinion 21-01.

> ***administration of covered countermeasures*** by a qualified person pursuant to a declaration by the Secretary, including one based upon a defendant's failure to obtain consent.
>
> Notably, Congress created an alternative administrative remedy—the Countermeasures Injury Compensation Program—for covered injuries stemming from countermeasures taken in response to the declaration of a public health emergency as well as a separate federal cause of action for wrongful death or serious physical injury caused by the willful misconduct of covered individuals or entities. The provision of these exclusive federal remedies further supports our finding of preemption.

Id. at 143-44. (Internal citations omitted) (emphasis added). The court, therefore, concluded that plaintiff's state law claims for negligence and battery were preempted by the PREP Act, and "inasmuch as the exclusive remedy under the statute is a federal cause of action to be brought in federal court, the complaint must be dismissed for lack of subject matter jurisdiction." *Id.* at 144-45.

Numerous federal courts have dismissed state law claims preempted by other federal statutes with immunity and exclusive remedy provisions similar to those found in the PREP Act on jurisdictional grounds. For example, the Federal Tort Claims Act ("FTCA"), like the PREP Act, provides an exclusive remedy under specified circumstances and immunizes federal employees from all liability for any negligent or wrongful acts or other common law tort claims committed while acting within the scope of their employment. *See* 28 U.S.C. § 2679(b)(1). The FTCA also acts as a limited waiver by the United State of its sovereign immunity and allows for a tort suit against the United States under specified circumstances. The FTCA provides an exclusive remedy for claims falling thereunder, 28 U.S.C. § 2679(b)(1), requiring that a claimant exhaust all administrative remedies before filing a complaint in federal district court. This requirement is jurisdictional and cannot be waived. *See Celestine v. Mount Vernon Neighborhood Health Ctr.*, 403 F.3d 76, 82 (2d Cir. 2005). Thus, courts have dismissed claims falling under the FTCA on

jurisdictional grounds where a claimant fails to exhaust these administrative remedies. *See, e.g., Leytman v. United States*, No. 19-3929, 2020 WL 6297440, at *2 (2d Cir. Oct. 28, 2020) [affirming dismissal of pending and unexhausted claims falling under FTCA for lack of subject matter jurisdiction]; *Davila v. Lang*, 343 F. Supp. 3d 254, 269–71 (S.D.N.Y. 2018) [dismissing claim under FTCA for lack of subject matter jurisdiction where plaintiff failed to exhaust administrative remedies]; *Hutchinson v. Young*, No. 08 CV 127(RJD)(LB), 2009 WL 10706592, at *2 (E.D.N.Y. Mar. 9, 2009) [dismissing medical malpractice claim against federal defendants for lack of subject matter jurisdiction where claim fell under the FTCA and plaintiff failed to exhaust administrative remedies required thereunder].

The purpose of the FTCA is to assure that "decisions and conduct of federal public servants in course and scope of their work will not be adversely affected by fear of personal liability for money damages and burden of defending damage liability claims." *Melo v. Hafer*, 13 F.3d 736, 744 (3d Cir. 1994). Similarly, as the Secretary and General Counsel of HHS has made clear, the PREP Act is designed to "remove legal uncertainty and risk" so as not to hinder the essential efforts of those frontline workers who continue to combat the "unprecedented global challenge" presented by COVID-19.[28]

Courts have similarly dismissed, as preempted, claims that implicate the Labor Management Relations Act ("LMRA"), which governs claims dependent on analysis of a collective-bargaining agreement, (*Shearon v. Comfort Tech Mech. Co.*, 936 F. Supp. 2d 143, 149 (E.D.N.Y. 2013) [dismissing state common law claims preempted by LMRA on jurisdictional grounds where claims were subject to the grievance and arbitration provisions]), and the Employee Retirement Income Security Act ("ERISA") (*Watson v. Consol. Edison of N.Y.*, 594 F. Supp. 2d

[28] *See* Advisory Opinion 20-04, p.1.

399, 409 (S.D.N.Y. 2009) [dismissing plaintiffs' fraud and fiduciary duty claims alleging misconduct by defendants in administration of employee benefit plans, as falling directly under ERISA's express preemption clause]).

And finally, in a case involving the National Childhood Vaccine Injury Act (NCVIA), the Supreme Court dismissed a products liability action brought against a vaccine manufacturer, finding that the NCVIA preempts all such design-defect claims brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011). The relevant provision of the NCVIA states:

> [n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, ***if*** the injury or death resulted from side effects that were unavoidable ***even though*** the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C.A. § 300aa–22(b)(1) (emphasis added). The Court found that given the plain language and intent of the statute, coupled with its legislative history and no-fault compensation program, the NCVIA preempts all design-defect claims against vaccine manufacturers, and thereby affirmed the dismissal of plaintiff's state law claims, despite the conditional clauses preceded by the terms "if" and "even though."

Significantly, in a dissenting opinion, Justice Sonia Sotomayor recognized that the PREP Act's categorical terms "shall" and "all" demonstrate an intent by Congress to unequivocally preempt and bar "all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure …." 42 U.S.C.A. § 247d-6d(a)(1). Justice Sotomayor distinguished the conditional language in the NCVIA from the absolute language in the PREP Act with respect to the preemptive effect of each:

> [i]ndeed, when Congress intends to pre-empt design defect claims categorically, it does so using categorical (*e.g.,* "all") and/or declarative language (*e.g.,* "shall"), rather than a conditional term ("if"). For example, in a related context, Congress has authorized the Secretary of Health and Human Services to designate a vaccine designed to prevent a pandemic or epidemic as a "covered countermeasure." 42 U.S.C. §§ 247d–6d(b), (i)(1), (i)(7)(A)(i). With respect to such "covered countermeasure[s]," Congress provided that subject to certain exceptions, "a covered person *shall* be immune from suit and liability under Federal and State law with respect to *all* claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure," § 247d–6d(a)(1) (emphasis added), including specifically claims relating to "the design" of the countermeasure, § 247d–6d(a)(2)(B).

Bruesewitz v. Wyeth LLC, 562 U.S. 223, 253 (2011) (*dissent*, J. Sotomayor) (emphasis in original).

Thus, despite plaintiff's attempts to avoid preemption by stylizing her claims under state law, any application of the PREP Act, as defined by the Declaration and its Amendments, to the Amended Complaint and the patient's medical records compel the conclusion that these claims necessarily arise under a federal statute.

The PREP Act provides exclusive grievance and remedy provisions mandating where and under what circumstances suit may be brought. Plaintiff cannot pick and choose her facts and claims in order to seek a "separate vehicle to assert a claim for benefits" outside of the PREP Act's remedial scheme. *See Aetna Health Inc. v. Davila*, 542 U.S. 200, 217-18 (2004). Indeed, plaintiff has not sought compensation under the Fund nor has she commenced a federal cause of action under the PREP Act in the United States District Court for the District of Columbia. 42 U.S.C.A. § 247d-6d(d)(e). These remedies are "exclusive of any other civil action or proceeding for any claim or suit [the PREP Act] encompasses." 42 U.S.C.A. § 247d-6e. Therefore, neither this, nor any other court, has subject matter jurisdiction over plaintiff's claims. Accordingly, OLOC respectfully asks this Court to dismiss the Amended Complaint, pursuant to F.R.C.P. 12(b)(1).

IV. PLAINTIFF'S CLAIMS ARE BARRED BY THE IMMUNITY PROVISIONS OF THE PREP ACT AND, THEREFORE, MUST BE DISMISSED

Plaintiff also fails to state an actionable claim against OLOC since it is expressly immune from suit under the facts as alleged and as set forth in the patient's medical records. Immunity applies "to any claim of loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C.A. § 247d-6d(a)(2)(B). Since plaintiff's "claim of loss" is causally related to the administration and use of multiple covered COVID-19 countermeasures, the PREP Act provides immunity to OLOC and affords it a defense that completely bars plaintiff's claims.

"An affirmative defense may be raised by a pre-answer motion to dismiss under Rule 12(b)(6) … if the defense appears on the face of the complaint." *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 74 (2nd Cir. 1998) [affirming dismissal under F.R.C.P. 12(b)(6) based on official immunity]. For example, in *Pani*, the Second Circuit rejected plaintiff's argument that F.R.C.P. 12(b)(6) dismissal was improper, claiming that dismissal was based on the grounds of the affirmative defense of official immunity, and ruled that the complaint made clear that the allegations against the defendant arose out of its role as a Medicare carrier, thereby entitling defendant to official immunity. *Id.* at 75. The court dismissed the complaint, pursuant to F.R.C.P. 12(b)(6). *See also Santos-Buch v. Fin. Indus. Regulatory Auth., Inc.,* 591 F. App'x 32 (2nd Cir. 2015) [affirming dismissal of claim for monetary damages against self-regulatory organization under Securities and Exchange Act, pursuant to F.R.C.P. 12(b)(1) and F.R.C.P. 12(b)(6), based on immunity of self-regulatory organization in connection with discharge of regulatory responsibilities].

Similarly, the allegations in the Complaint here implicate the PREP Act, including the immunity afforded OLOC thereunder. As a result, plaintiff's Amended Complaint must be dismissed for failure to state a claim, pursuant to F.R.C.P. 12(b)(6).

V. ALTERNATIVELY, PLAINTIFF'S CLAIMS ARE BARRED BY THE EDTPA AND MUST BE DISMISSED

Even if this Court does not find that plaintiff's claims are barred by the PREP Act, the Amended Complaint should still be dismissed because it is unsustainable under state law, pursuant to the EDTPA. In order to promote public health and prioritize medical treatment to all citizens during the emergency created by COVID-19, the EDTPA broadly protects health care facilities such as OLOC from liability that may result from an act or omission "in the course of arranging for or providing health care services" during this emergency. N.Y. Pub. Health Law § 3080 (McKinney). Immunity applies where the alleged act or omission occurs under circumstances where the facility: 1.) is providing services pursuant to a COVID-19 emergency rule; 2.) the treatment of the patient ***is impacted by the health care facility's decisions or activities in response to the COVID-19 outbreak*** and in support of the state's directives; and 3.) is providing services in good faith. N.Y. Pub. Health Law § 3082(1) (McKinney). "Health care services" expressly include services that relate to "the diagnosis, ***prevention***, or treatment of COVID-19". N.Y. Pub. Health Law § 3082(2) (McKinney) (emphasis added).

Here, plaintiff alleges that OLOC "failed to take proper precautions to help prevent the development of infections prior to and leading up to the COVID-19 pandemic", and that its failure to "maintain a system for preventing, identifying … and controlling infections" led to the death of the patient from COVID-19. (*See* Amended Complaint, at ¶¶ 1, 4). Plaintiff claims that the patient's death was impacted by the decisions and activities of OLOC related to the prevention of COVID-19. These allegations implicate acts and omissions and resulting injury in the course of

arranging for and providing health care services during the COVID-19 emergency. Therefore, by the express language of the EDTPA, plaintiff's claims are barred and must be dismissed.

Plaintiff cannot avoid dismissal by alleging that these acts and omissions occurred prior to March 7, 2020, the effective date of the EDTPA, and also the date of Governor Cuomo's Executive Order No. 202, which declared a Disaster Emergency in the State of New York due to COVID-19. On the contrary, under New York law, "a tort cause of action cannot accrue until an injury is sustained." *Kronos, Inc. v. AVX Corp*., 81 N.Y.2d 90, 94 (1993). Based on the allegations in the Amended Complaint, no cause of action accrued herein until the patient was diagnosed with COVID-19. Thus, plaintiff cannot base her claims on allegations of tortious conduct prior to March 7, 2020. Accordingly, the EDTPA bars plaintiff's claims and requires dismissal of the Amended Complaint.

VI. PLAINTIFF CANNOT MAINTAIN A CLAIM FOR WILLFUL MISCONDUCT OR GROSS NEGLIGENCE

In the Amended Complaint, plaintiff summarily concludes, without any factual support, that OLOC "acted in so careless a manner as to show complete disregard for the rights and safety of others", and that this conduct was willful, in reckless disregard and constitutes gross negligence. (*See* Amended Complaint, ¶¶ 136-153). This claim fails as a matter of law under both the PREP Act and the EDTPA.

As to the former, for a claim to rise to the level of willful misconduct under the PREP Act, plaintiff must allege an act or omission that is taken: "(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." Only then may a claimant pursue a federal cause of action under the PREP Act in the United States District Court for the District of Columbia after seeking relief pursuant to the Fund. *See* 42

U.S.C.A. § 247d-6d(c)(d)(e). Thus, plaintiff's claim for gross negligence may not be brought in this Court and must, therefore, be dismissed.

As for the EDTPA, the only exception for immunity is if "the harm or damages were caused by an act or omission constituting willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm …." N.Y. Pub. Health Law § 3082(2) (McKinney). Here, plaintiff does not allege any facts to support a claim that her alleged injuries were caused by gross negligence or intentional infliction of harm.

Gross negligence, requires a showing of "'conduct that evinces a reckless disregard for the rights of others or smacks of intentional wrongdoing.'" *Estiverne v Esernio-Jenssen*, 910 F Supp.2d 434, 445 (E.D.N.Y. 2012) (*quoting Colnaghi, USA. v. Jewelers Protection Servs., Ltd*., 81 N.Y.2d 821, 823–24 (1993)). There is no showing in the Complaint that OLOC's conduct was "intentional, malicious, outrageous, or otherwise aggravated beyond mere negligence" or that it acted wantonly or maliciously. *See Graham v. Colombia Presbyterian Med. Ctr.*, 185 A.D.2d 753 (1st Dept. 1992); *Anzolone v. L.I. Care Center*, 26 A.D.3d 449 (2nd Dept. 2006).

Conclusory allegations regarding purportedly reckless conduct, "unsupported by any factual allegations of conduct evincing a reckless disregard for the rights of others or smacking of intentional wrongdoing, [are] insufficient to state a cause of action alleging gross negligence." *Mancuso v. Rubin*, 52 A.D.3d 580, 583 (2nd Dept. 2008). *See also Amadsau v. Bronx Lebanon Hosp. Ctr.,* No. 03 CIV.6450 LAK AJP, 2005 WL 121746, at *13 (S.D.N.Y. Jan. 21, 2005), *report and recommendation adopted sub nom. Amadasu v. Rosenberg*, No. 03CIV.6450LAK, 2005 WL 954916 (S.D.N.Y. Apr. 26, 2005), *aff'd,* 225 F. App'x 32 (2nd Cir. 2007) [plaintiff's conclusory assertions of recklessness and gross negligence were too conclusory and unsupported by any evidentiary fact to survive motion to dismiss]; *Sutton Park Dev. Corp. Trading Co. Inc. v. Guerin*

& Guerin Agency Inc., 297 A.D.2d 430, 431 (3rd Dept. 2002) [dismissing claim for gross negligence where complaint failed to include any factual averments alleging conduct of aggravated character amounting to reckless disregard].

Thus, the Amended Complaint does not set forth a plausible claim for willful misconduct or gross negligence, which may warrant an exception to immunity under the EDTPA, providing yet an additional basis for dismissal.

CONCLUSION

WHEREFORE, for the foregoing reasons, Defendants OUR LADY OF CONSOLATION GERIATRIC CARE CENTER, OUR LADY OF CONSOLATION GERIATRIC CARE CENTER d/b/a OUR LADY OF CONSOLATION NURSING AND REHABILITATIVE CARE CENTER and OUR LADY OF CONSOLATION NURSING AND REHABILITATIVE CARE CENTER respectfully request that the Amended Complaint against them be dismissed with prejudice, along with such other and further relief as this Court deems just and proper.

Dated: Garden City, New York
February 5, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 5, 2021, a copy of the foregoing**, NOTICE OF MOTION, DECLARATION, supporting exhibits** and **MEMORANDUM OF LAW** were served upon the following party via e-mail:

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